

Remarks

Claim Amendments

Claims 1, 14, 20, 41, 47, 53, and 63 have been amended. Each of claims 1, 14, 20, 41, 47, 53 and 63 has been amended to specify that the “superior articular facet” of the claims is a natural facet, *i.e.*, a facet of a vertebra of a human spine. In addition, claims 20, 41, and 63 have been amended to require that the inferior device be secured to the inferior implant and to the inferior articular facet and to the side of the spinous process of the vertebra opposite the inferior articular facet. It is respectfully submitted that Reiley does not teach or suggest the limitations of any of the pending claims. Nor do any of the previously cited or submitted references, either alone or in combination, teach or suggest the limitations of any of the pending claims.

Rejections - 35 U.S.C. § 102(e)

Claims 1-2, 4-11, 14-20, 41-61 and 63 were rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Reiley (US Patent Publication Number 2002/0123806; cited by Applicant). It is respectfully requested that the Examiner’s rejection be withdrawn.

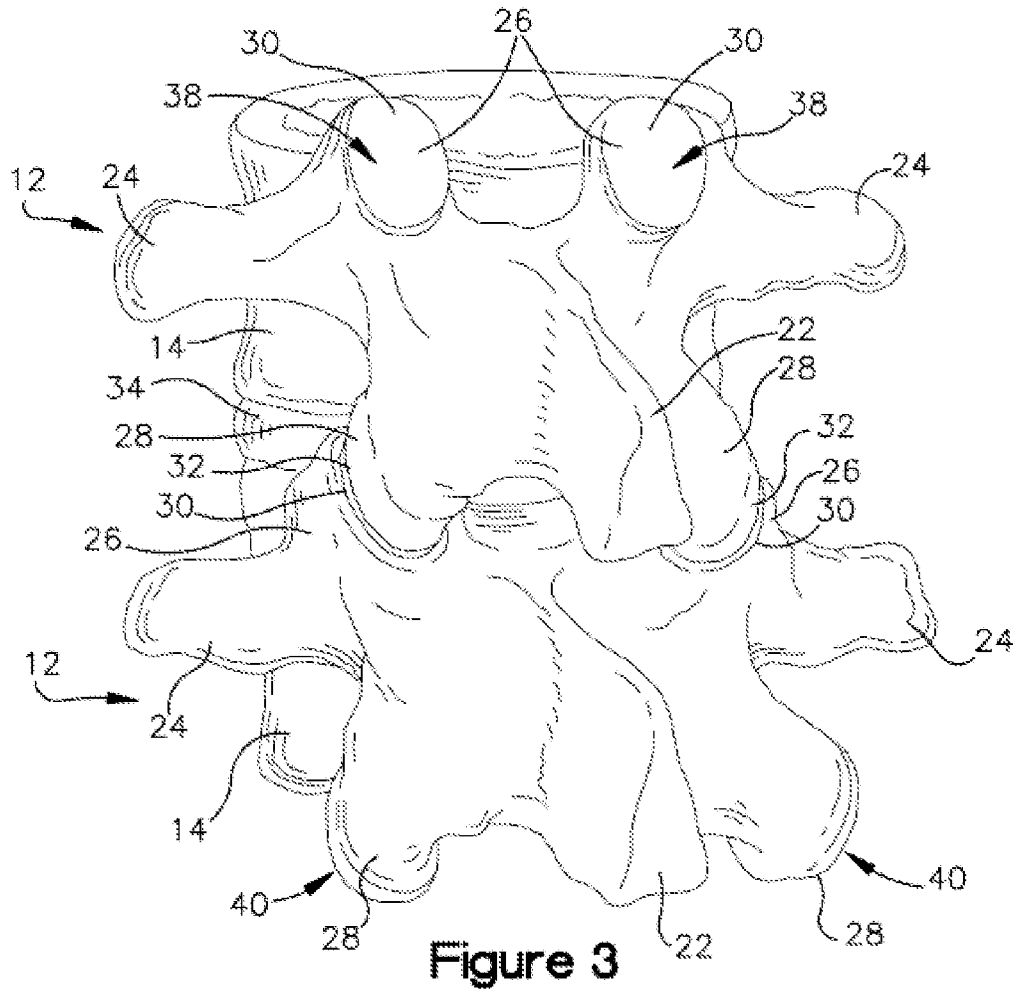
The present invention relates to providing an artificial articulating surface on a facet (inferior and/or superior). Independent claims 1, 14, 20, 53 and 63 each recite superior and inferior implants “***configured for placement on***” an ***articular facet***. And independent claims 41 and 47 each recite means for “***providing an artificial articulating surface on***” superior and inferior ***articular facet***. As explained in Applicant’s previous submissions, Reiley does not teach or suggest any implant configured for placement on an articular facet, nor does Reiley teach or suggest any means for providing an artificial articulating surface on an articular facet. None of the structures disclosed in Reiley are capable of being placed on an articular facet. Instead, Reiley discloses a facet replacement system and actually teaches away from the claimed invention because Reiley requires the resection of the articular facet being treated.

Anatomy of the Lumbar Spine

As explained in the background section and illustrated in Figure 3 of the present application, the laminae of the spine have various structures, including the superior facet, inferior facet, superior articulating surface and inferior articulating surface. Notably, structures 30 and 32 of Figure 3 are the “articular facets” referenced in the claims of the present invention:

Turning now to Figures 2 and 3, normal human lumbar vertebrae 12 are illustrated. It will be understood by those skilled in the art that while the lumbar vertebrae 12 vary somewhat according to location, they share many features common to most vertebrae 12. Each vertebra 12 includes a vertebral body 14. Two short bones, the pedicles 16, extend backward from each side of the vertebral body 14 to form a vertebral arch 18. At the posterior end of each pedicle 16, the vertebral arch 18 flares out into broad plates of bone known as the laminae 20. The laminae 20 fuse with each other to form a spinous process 22. The spinuous process 22 provides muscle and ligament attachment.

The transition from the pedicles 16 to the laminae 20 is interrupted by a series of processes. Two transverse processes 24 thrust out laterally on each side from the junction of the pedicle 16 and the lamina 20. The transverse processes 24 serve as guides for the attachment of muscles to the vertebrae 12. Four articular processes, two superior 26 and two inferior 28, also rise from the junctions of the pedicles 16 and the laminae 20. The superior articular processes 26 are oval plates of bone rising upward on each side from the union of the pedicle 16 with the lamina 20. The inferior processes 28 are oval plates of bone jutting downward on each side. The superior and inferior articular processes 26 and 28, respectively, each have a natural bony structure known as a facet. The superior articular facet 30 faces upward, while the inferior articular facet 32 faces downward. The superior articular facet 30 and the inferior articular facet 32 have articulating surfaces 38 and 40, respectively.



Bogduk, Nikolai, Clinical Anatomy of the Lumbar Spine and Sacrum, 4th ed. Elsevier, Churchill, Livingstone; 2005 (Ex. A to the October 12, 2009 Response to the Examiner's August 18, 2009 Office Action) is also instructive:

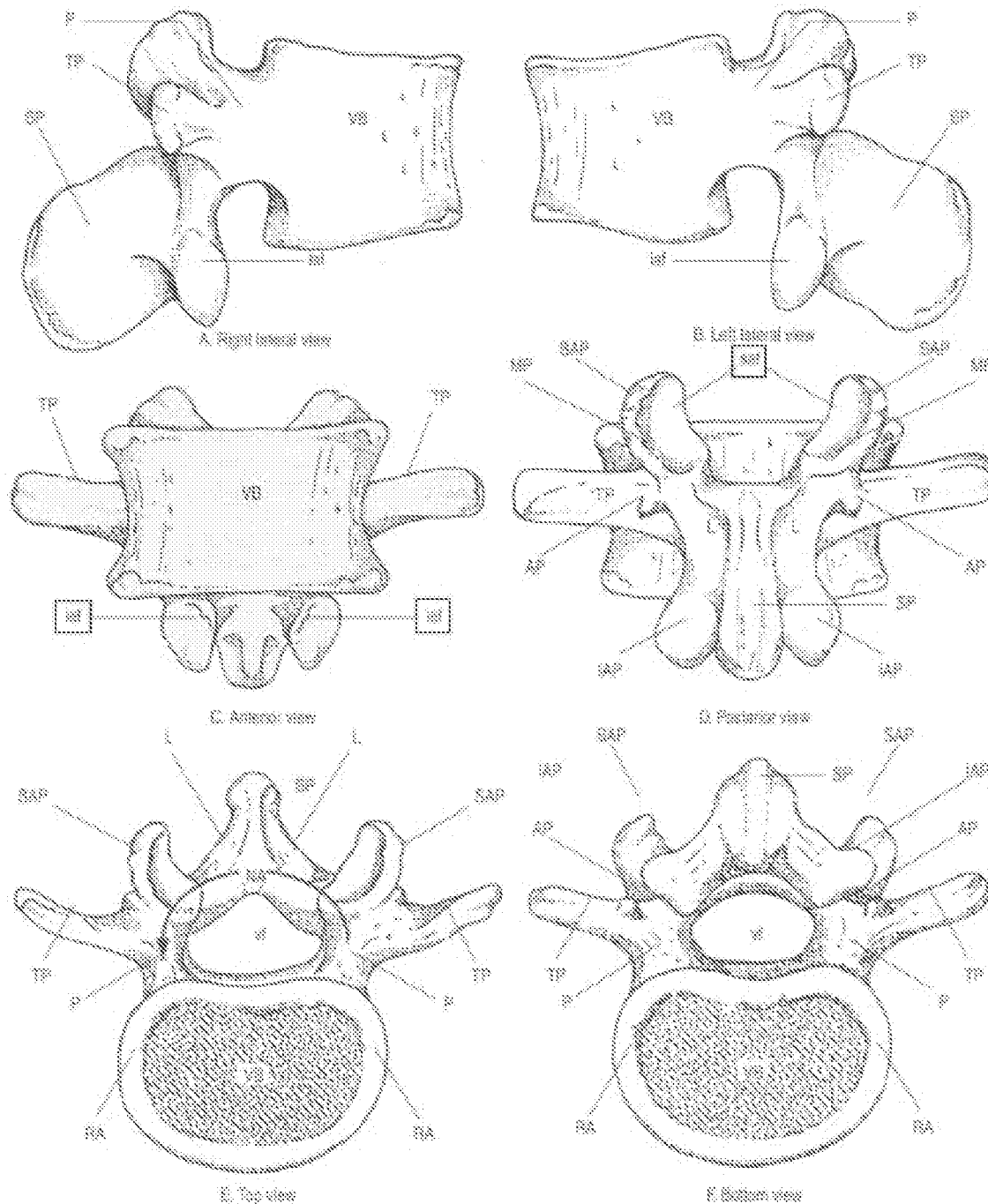


Figure 1.2 The parts of a typical lumbar vertebra: AP, accessory process; IAF, inferior articular facet; IAP, inferior articular process; L, lamina; MP, mammillary process; RA, neural arch; P, pedicle; RA, ring apophysis; SAP, superior articular facet; SAP, superior articular process; SP, spinous process; TP, transverse process; VB, vertebral body; vl, vertebral lamina.

Reiley does not teach or suggest the limitations of any of independent claims 1, 14, 20, 41, 47, 53, and 63

Unlike the present invention, Reiley is directed to an apparatus that **replaces** the articular facet, not an apparatus configured for **placement on** an articular facet.

Figures 1 and 2 of Reiley are depictions of vertebrae and Figures 3-5 and 7-9 illustrate the devices of Reiley as they are used to treat vertebrae. It is clear in each of Figures 3-5 and 7-9 that the entire facet (superior or inferior) is resected and the apparatus of Reiley replaces the removed facet.

To remove any doubt regarding the nature of the Reiley device, Reiley explains throughout the specification that the prosthetic system is for replacing facet structures. Reiley refers to replacing the caudal portion or cephalad portion of the facet joint. As Reiley explains, this means either the entire superior half of the joint or the entire inferior half of the joint:

“..... a given natural facet joint has a superior half and an inferior half..... the **superior half** of the joint is formed by the vertebral level below the joint (Which can thus be called the **caudal portion** of the facet joint, i.e. because it is near the feet). The **inferior half** of the joint is formed by the vertebral level above the joint (Which can thus be called the **cephalad portion** of the facet joint, i.e. because it is near the head).” (¶13, emphasis added).

Thus, the “superior articular facet” of the present invention is on the cephalad portion of the joint and the “inferior articular facet” of the present invention is on the caudal portion of the joint. Indeed, from Reiley’s definition of the “caudal portion” and “cephalad portion” of the facet joint, it is clear that Reiley discloses only a system for replacing either the entire superior half of the joint or the entire inferior half of the joint:

“There is a need in the field for prostheses and prosthetic systems to **replace** injured and/ or diseased facet joints.....” (¶1, emphasis added).

“One aspect of the invention provides for a facet joint prosthesis to **replace**, on a **vertebral body**, a **caudal portion** of a **natural facet joint** (e.g. a superior articular surface **and** supporting bone structure on the vertebral body). ... the caudal prosthesis includes an artificial facet joint structure adapted to **replace** a caudal portion of the natural facet joint after its **removal** from the vertebral body. The **removal** of a caudal portion of the natural facet joint and its **total replacement** by the artificial facet joint structure of the caudal prosthesis, frees the orientation of the prosthesis from anatomic

constraints imposed by a preexisting articular configuration of the **caudal portion of the natural facet joint**". (§15, emphasis added).

"This aspect of the invention also provides a method of **replacing** on a **vertebral body**, a **caudal portion** of a **natural facet joint**. The method **removes** a caudal portion of the natural facet joint from the **vertebral body**, and, **in its place**, fixes a component to the **vertebral body** that includes an artificial facet joint structure adapted to **replace** the **removed** caudal portion of the **natural facet joint**. Desirably, the artificial facet joint structure includes an artificial articular configuration **unlike** the preexisting articular configuration of the **removed caudal portion of the natural facet joint**." (§16, emphasis added).

Another aspect of the invention provides a facet joint prosthesis to **replace**, on a **vertebral body**, a **cephalad portion** of a **natural facet joint** e.g. an inferior articular surface and supporting bone structure on the vertebral body). The cephalad prosthesis comprises a component sized to be fixed to the vertebral body, e.g. on or near a pedicle, or on or near a lamina or combinations thereof. The cephalad prosthesis includes an artificial facet joint structure adapted to replace a cephalad portion of the natural facet joint after its removal from the vertebral body. ... The **removal** of a cephalad portion of the natural facet joint and its **total replacement** by the artificial facet joint structure of the cephalad prosthesis, frees the orientation of the prosthesis from anatomic constraints imposed by a preexisting articular configuration of the **cephalad portion of the natural facet joint**". (§17, emphasis added).

"This aspect of the invention also provides a method of **replacing** on a **vertebral body**, a **cephalad portion** of a **natural facet joint**. The method **removes** a cephalad portion of the natural facet joint from the **vertebral body**, and, **in its place**, fixes a component to the **vertebral body** that includes an artificial facet joint structure adapted to **replace** the **removed** cephalad portion of the **natural facet joint**. Desirably, the artificial facet joint structure includes an artificial articular configuration **unlike** the preexisting articular configuration of the **removed cephalad portion of the natural facet joint**." (§18, emphasis added).

Another aspect of the invention provides a prosthesis assembly and related method for **replacing** a natural facet joint between adjoining first vertebral body and a second vertebral bodies. ... the first component includes a first artificial facet joint structure adapted to **replace** a cephalad portion of the natural facet joint **on the first vertebral body** after **removal** of the **cephalad portion of the natural facet joint** from the first vertebral body. ... the second component includes a second artificial facet joint structure adapted to **replace** the caudal portion of the **natural facet joint** of the second vertebral body **after removal** of the caudad portion of the **natural facet** from the second vertebral body". (§19, emphasis added).

“Fig. 3 shows a caudal facet **joint replacement prosthesis** 26 ... it creates an artificial facet joint structure 28 for the superior half of a facet **joint replacement**. The caudal prosthesis 26 allows for the **removal and replacement** of injured, diseased and/or deteriorating natural superior articular surfaces **and** supporting boney structure on the vertebral body **below the facet joint...**” (§39, emphasis added).

“... in the preferred embodiment, the prosthesis 26 is used to **replace** the caudal portion of one or more facet joints.” (§60, emphasis added).

“A surgical procedure **removes and replaces** the caudal portion of a facet joint with the caudal prosthesis 26....” (§64, emphasis added).

“Fig 9 shows a cephalad facet joint **replacement** prosthesis 48 ... the cephalad prosthesis 48 allows for the **removal and replacement** of injured, diseased, and/or deteriorating natural inferior articular surfaces **and** supporting boney structure on the vertebral body above the facet joint...” (§70, emphasis added).

“The cephalad prosthesis 48 shown in fig 9 desirably spans the lamina 16 from the left side of the vertebral body 10 to the right side of the vertebral body 10. ... The cephalad prosthesis 48 allows for **replacement** of diseased and deteriorating inferior portions of the vertebra and **partial replacement of lamina**... the cephalad prosthesis 48 creates **artificial** facet joint structure elements 50 for the **inferior half of facet joints** in the spine...” (§73, emphasis added).

Reiley also makes clear that the disclosed apparatus is configured for attachment to the lamina and pedicle—not the inferior or superior facet:

“The cephalad prosthesis 48 as described above is placed **over** the spinous process 18 **over** the lamina 16. The cephalad prosthesis 48 is **attached** as above described to the **lamina 16 and to each pedicle**. The cephalad prosthesis 48 may also be further attached to the **spinous process** 18 with a transspinous process screw 66 to provide additional stability,...” (§98, emphasis added).

Finally, Reiley leaves no doubt that the superior or inferior facet **must be removed** in order to install the apparatus:

“...**because the caudal portion of the natural facet joint has been removed**, the artificial facet joint structure of the caudal prosthesis 26 can be installed in a desired position....” (§66, emphasis added).

“Because the cephalad portion of the **natural facet joint** is **removed**...” (§74, emphasis added).

“As fig 9 shows, the caudal prosthesis 26, e.g. as described above, may also be installed with the cephalad prosthesis 48, to **replace** both the caudal and cephalad portions of the natural facet joint, **after both caudal and cephalad portions of the natural facet joint are surgically removed**. Together, the caudal and cephalad prostheses 26 and 48 form a **total facet replacement system 52**.” (§75, emphasis added).

“Because the system 52 entails **removal** of **both** the caudal and cephalad portions of the **natural facet joints**,...” (§76, emphasis added).

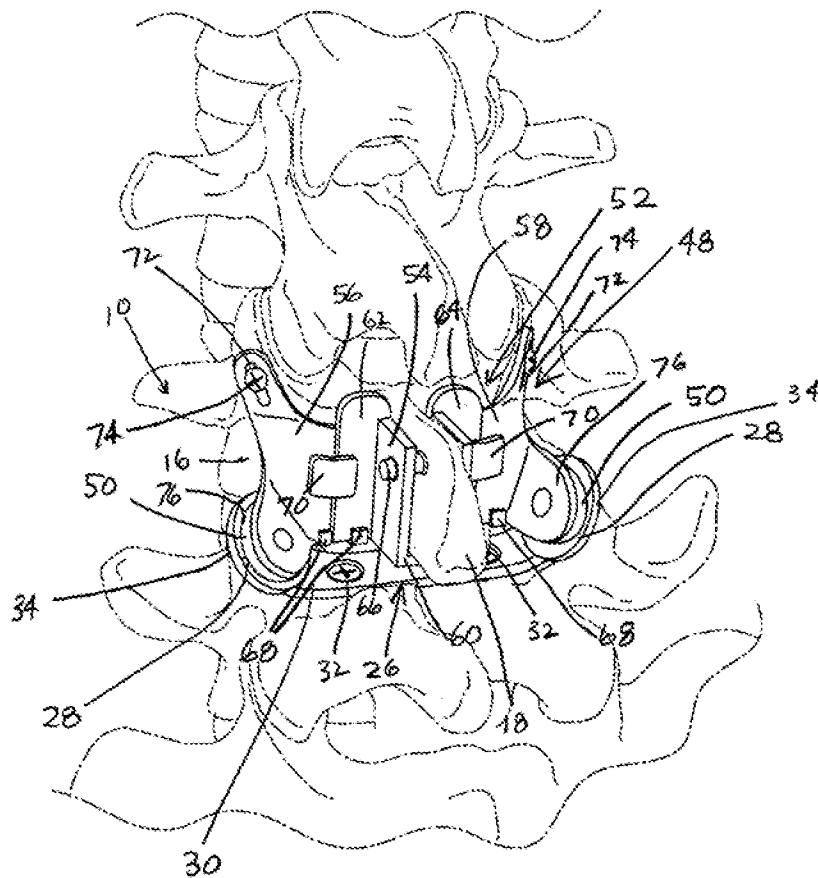


Fig. 9

Accordingly, it is respectfully submitted that Reiley neither teaches nor suggests an apparatus “**configured for placement on**” an **articular facet** as set forth in any independent claims 1, 14, 20, 53 or 63. It is also respectfully submitted that Reiley neither discloses nor suggests “**providing an artificial articulating surface on**” an

articular facet as set forth in any of independent claims 41 or 47. Indeed, it would be impossible to place the device of Reiley on an articular facet or to use the device of Reiley to provide an artificial articulating surface on an articular facet without severely damaging the spine, causing paralysis and possibly death. Reiley could not be more clear. The device of Reiley is a facet replacement system—not a device capable of being placed on a facet.

The Examiner's rejection under 35 U.S.C. §102(e) should be withdrawn.

Reiley does not teach or suggest any structure capable of securing the inferior implant to the inferior articular facet and to the side of the spinous process of the vertebra opposite the inferior implant.

Independent claims 20, 41, and 63 have been amended to require that the inferior device (e.g., the inferior implant or inferior means) be secured to the inferior articular facet and to the side of the spinous process of the vertebra opposite the inferior articular facet:

- Claim 20 includes “a translaminar fixation mechanism adapted to secure the inferior implant to the inferior articular facet and to bone on the side of the spinous process of the vertebra opposite the inferior implant via a lamina adjacent to the inferior articular facet.”
- Claim 41 includes “means for securing the inferior means to the inferior articular facet and to bone on the side of the spinous process of the vertebra opposite the inferior means via a lamina adjacent the inferior articular facet.”
- Claim 63 includes “a fixation mechanism adapted to secure the inferior implant to the inferior articular facet by traversing a lamina connected to the inferior articular facet such that the inferior implant is secured to bone on the side of the spinous process of the vertebra opposite the inferior implant.”

In addition to the fact that the inferior joint structure (arm components 56 and 58 of Reiley) is not capable of being placed on an inferior articular facet, Reiley does not

disclose any structure capable of securing such structure (56 or 58) to both the inferior articular facet and to bone on the side of the spinous process opposite the inferior articular facet. While Figure 9 of Reiley discloses a structure passing through the spinous process, that structure does not secure and is not capable of securing any other structure to the inferior articular facet or to the lamina.

Thus, for this additional reason the Examiner's rejection under 35 U.S.C. §102(e) should be withdrawn. Claims 1-2, 4-11, 14-20, 41-61 and 63 are in condition for allowance.

Rejections - 35 U.S.C. § 103

Claims 3, 12 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Reiley. For the reasons discussed above, Reiley does not meet the limitations of the independent claims.

Accordingly, it is respectfully submitted that claims 3, 12 and 13 are in condition for allowance.

Louis does not teach or suggest the limitations of any of independent claims 1, 14, 20, 41, 47, 53, and 63

Applicant previously submitted Louis (WO 0301618), published in French, which was cited in a Japanese office action, and an English translation of the publication. It is submitted that Louis fails to teach or suggest the limitations of the claims for the same reason as Reiley. As explained above, the present invention relates to providing an artificial articulating surface on a facet (inferior and/or superior). Independent claims 1, 14, 20, 53 and 63 each recite superior and inferior implants “***configured for placement on***” an ***articular facet***. And independent claims 41 and 47 each recite means for “***providing an artificial articulating surface on***” superior and inferior ***articular facet***. Louis is merely another example of a device that requires resection of the facet—**it is not capable of being placed on or secured to an inferior articular facet as required by the claims.**

Louis clearly explains that a portion (if not all) of the inferior articular facet (identified as the caudal zygapophysis) must be excised (removed):

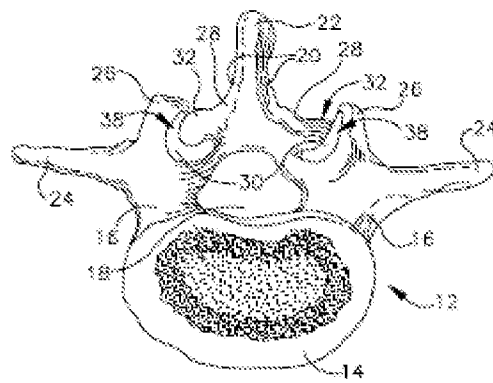
At least a partial excision (or ablation) of the joint processes is required.

On the caudal zygapophysis (or joint process) (or lower joint process of the overlying vertebra) ***a subtotal ablation is performed with an oblique section towards the vertebral lamina and perpendicular to the pars interarticularis***, and two anchor holes, one sagittally in the axis of the pars interarticularis towards the vertebral pedicle, and the other transversally within the thickness of the vertebral lamina, hollowed out starting from the spinous process.

(Louis, Page 7, line 29 – Page 8, line 2, emphasis added).

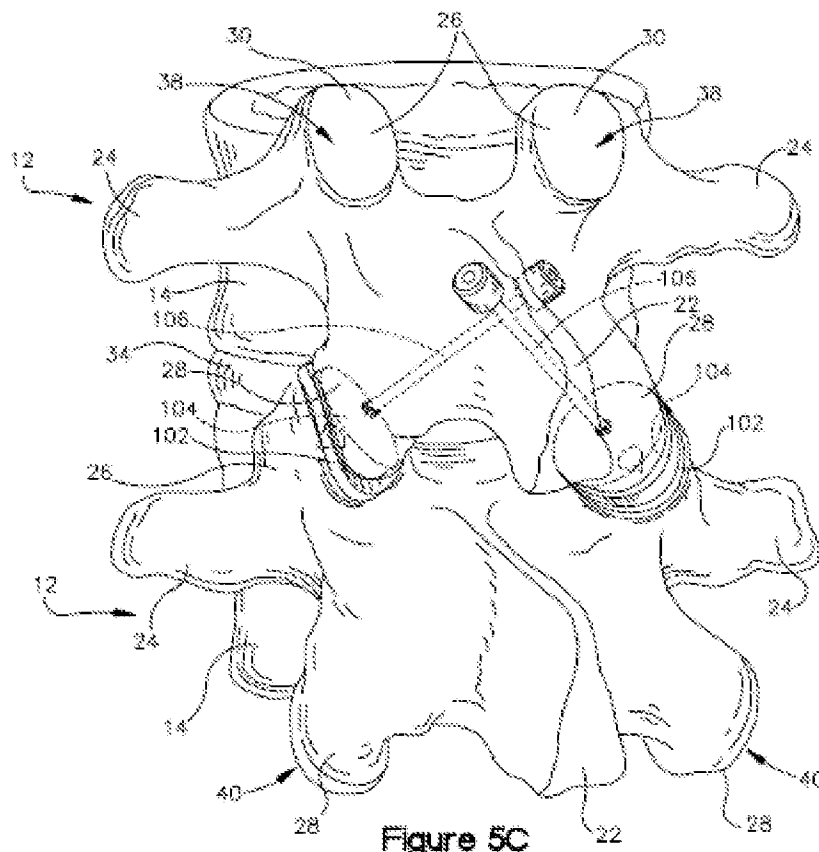
Because at least a portion of the inferior facet must be removed, the inferior implant is not “configured for placement on an inferior articular facet” as required by the claims. Instead, it is “configured to replace an inferior facet.” Moreover, there is no suggestion in Louis that any type of implant could be used without first removing part of the facet. In fact, it would be exceedingly difficult, if not impossible, to fix an implant such as that described in Louis to the pars interarticularis without damaging the patient unless a significant portion of the facet is removed prior to fixing the implant. The articular facets of the spine (identified in the present invention as elements 30 and 32) cannot be separated much without risking injury to a patient’s spinal cord. Accordingly, because of their shape, the manner in which they are anchored, and the manner in which they are designed to articulate, excision of at least part, if not all, of the facet is required in order to install the implants of Louis. There is no other means for creating sufficient space to accommodate the implant of Louis.

Moreover, Louis does not include a “a translaminar fixation mechanism 106 adapted to secure the inferior implant 104 to the inferior articular facet” as recited in claim 1 as amended. In order to understand the nature of the claim limitation, it is important to understand the elements of the vertebra. The laminae (illustrated as elements 20 in the present application—see Figure 2) are parts of the spine between the spinous process (illustrated as element 22 in the present application).

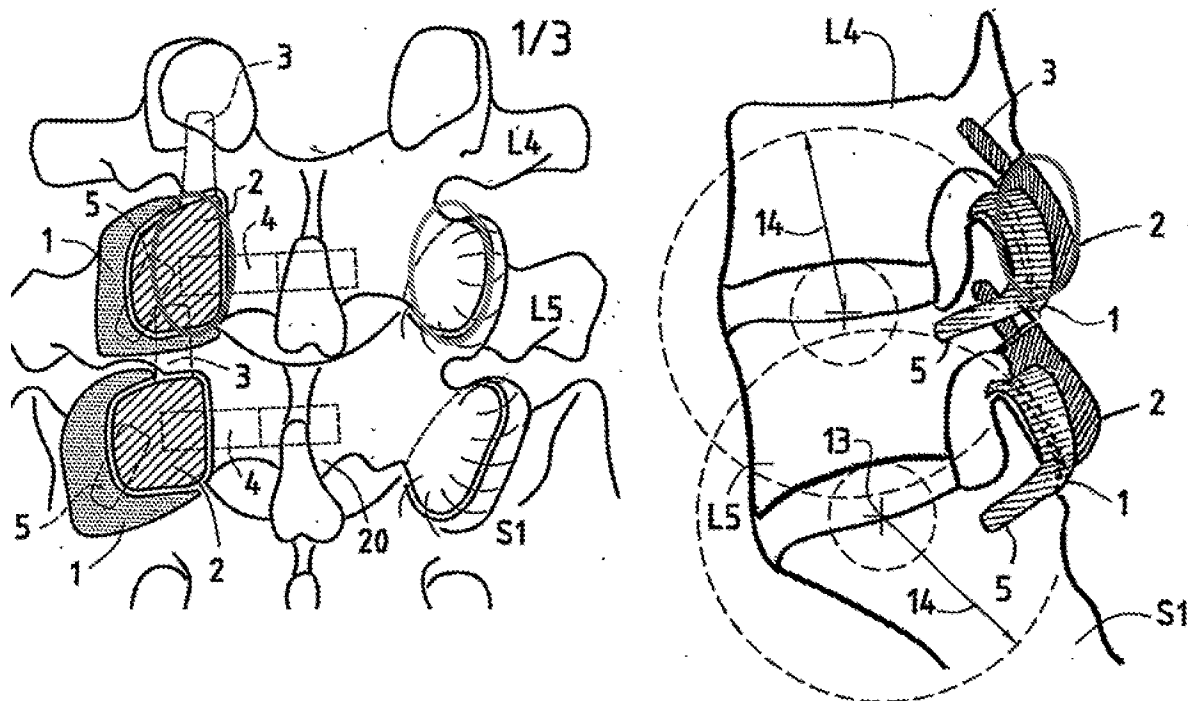


(See also the figures from Clinical Anatomy of the Lumbar Spine and Sacrum reproduced above.)

The claim limitation above is best illustrated in Figure 5C of the present application. Figure 5C clearly shows the implant 104 being fixed to the inferior articular facet 28 by the translaminal fixation mechanism 106.



In contrast, it is clear that the inferior articular facet must be exised in order to place the implant of Louis.

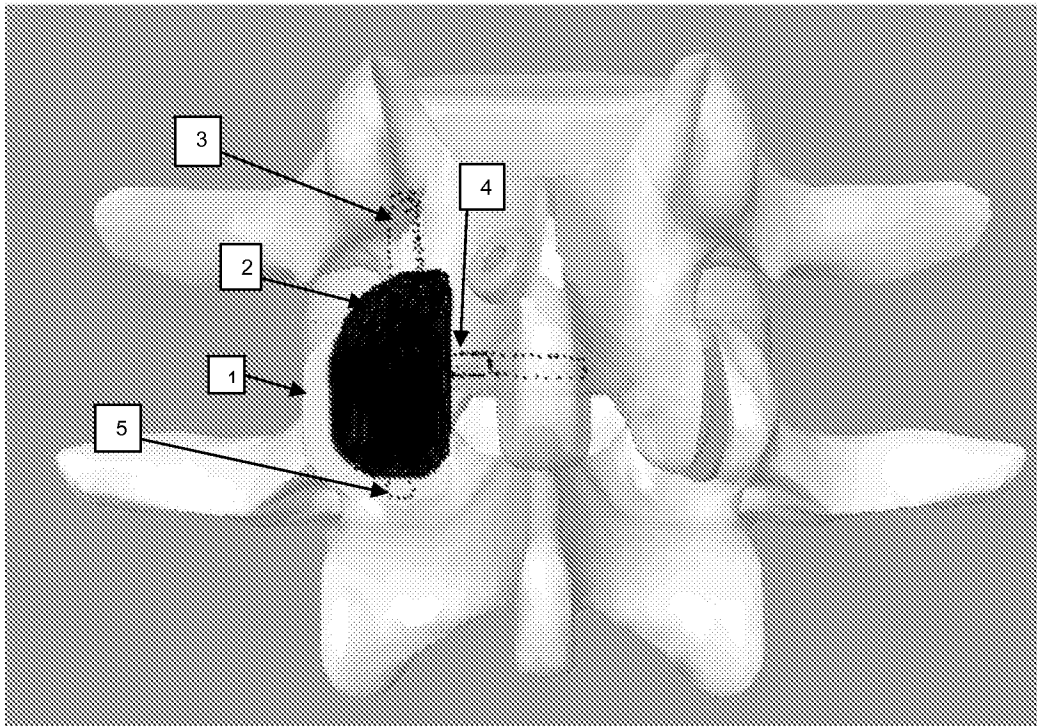


As shown in Figures 1 and 4 from Louis reproduced above, the inferior articular facet (indicated with a green oval) exists only on one side of the vertebra. On the side of the vertebra with the implant, the inferior articular facet is removed (indicated with a red oval). The specification also confirms that it is **necessary** to remove the inferior articular facet. ('168 Reference, Page 7, line 29 – Page 8, line 2.)

There is no question that Louis does not disclose any inferior implant configured for placement on an inferior articular facet.” There is also no question that Louis does not disclose any fixation mechanism “adapted to secure an implant to the inferior articular facet.” Louis simply does not teach or suggest an inferior implant capable of being placed on and secured to an inferior articular facet.

Moreover, there is no suggestion in Louis that a translaminar fixation mechanism of the type claimed would be a useful variation on the disclosed device. In fact, the device of Louis would fail if one were to use a translaminar fixation mechanism of the type claimed in the present invention with the device disclosed in Louis. The figure

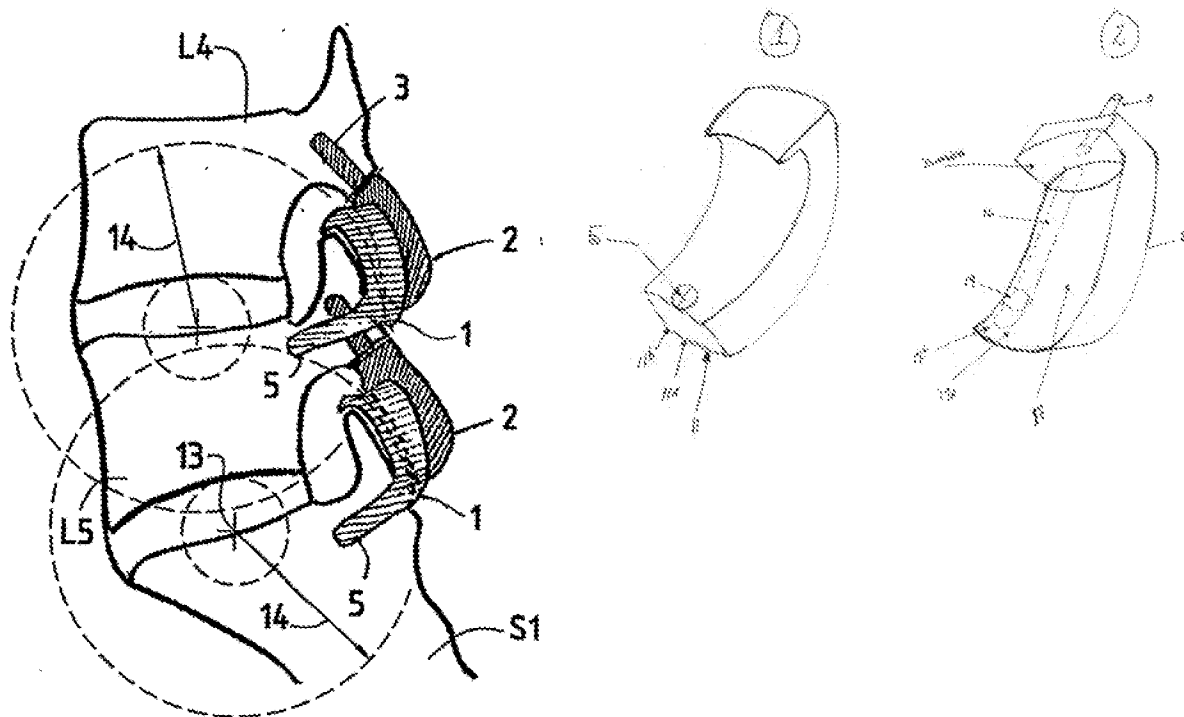
below provides an illustration of the fixation of the implant of Louis as compared to the device of the present invention.



Unlike the present invention, the implant 2 of Louis replaces the inferior articular facet, which must be excised prior to implantation. The implant 2 of Louis is designed to be fixed to the pars interarticularis by stud 3, which is part of the implant 2. Similarly, the implant 1 is designed to be fixed to the pedicle by stud 5, which is part of the implant 1. Stud 4 prevents implant 2 from dislodging from the pars interarticularis. Stud 4 merely traps the implant—it is not fixed to the implant. This is key. Because of the design of implant, if stud 4 were designed to fix implant 2 to the lamina opposite implant 2 (like the translaminar fixation mechanism claimed) increased strain would occur at the junction of stud 4 and implant 2 each time the patient moves from front to back, which would cause the device to fail.

A translaminar fixation mechanism of the type disclosed and claimed in the present invention simply would not work with a device of the type disclosed in Louis.

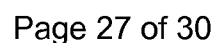
The inventors of Louis went to great lengths to avoid fixing any implant to the inferior articular facet. Instead, the inventors intended the primary point of fixation to be the pars interarticularis above the inferior facet—not to the inferior articular facet itself, which is removed prior to implantation. To accomplish the desired fixation, the inventors included a dihedron on implant 2 to prevent implant 2 from disengaging from the pars interarticularis. For clarity, Figure 4 of Louis and sketches of the implants 1 and 2 are provided below.



In addition, the device of Louis includes a stud 4 which also functions to prevent implant 2 from disengaging from the pars interarticularis, but is not fixed to implant 2. There is simply no suggestion in Louis that it might be useful to fix an implant **to the inferior articular facet** (which Louis teaches must be removed prior to implantation of implant 2). The present invention is not an obvious modification of the design of Louis. Securing the inferior implant to the inferior articular facet would be impossible according to Louis, which requires excision of the inferior facet.

It is clear that the inventors of Louis recognized that a hole can be drilled through the spinous process for the purpose of implanting a stud type fixation mechanism (stud 4) to hold implant 2 in a desired position (to trap the implant). ***It is equally clear that***

Moreover, Louis certainly does not teach or suggest any mechanism for securing an inferior device to the inferior articular facet and to the side of the spinous process of the vertebra opposite the inferior articular facet. The figure below illustrates the disclosure of Louis. The stud 4 of Louis is highlighted in orange. The area highlighted blue is the part of a hole that was created for the stud 4. The stud 4 clearly terminates partway through the hole, leaving the area highlighted blue as the portion of the hole not occupied by the stud 4. There is no question that the stud 4 does not traverse the spinous process to the lamina on the opposite side of the spinous process—and certainly the stud 4 cannot secure any implant to the lamina on the opposite side of the spinous process.



It is clear that Louis does not teach or suggest the limitations of the claims of the present invention, just as Reiley does not teach or suggest the limitations of the claims of the present invention.

Status of the Application

The USPTO has now issued **eight** office actions during almost 7 years of prosecution in which the actions of the USPTO have resulted in unnecessary delay and costs. Prior to the first office action (issued February 8, 2006), **Applicant submitted Reiley to the USPTO in an August 19, 2003 IDS**. Reiley was reviewed by Examiner Reimers prior to issuance of the first office action on **February 9, 2006**. Indeed, Examiner Reimers determined that Reiley neither anticipated the claims nor rendered the claims obvious. Notably, the claims were broader than the pending claims.

After numerous office actions involving Soboleski (US App. No. 2002/0151895), Applicant followed the present Examiner's suggestion and successfully overcame the rejection based on Soboleski. Unfortunately, the present Examiner responded by issuing a new rejection based on Reiley—**which was previously examined and deemed to not anticipate or render obvious even the broader original claims**. This is exactly the type of piecemeal examination that the MPEP clearly instructs “should be avoided.” MPEP 707.07(g).¹

Applicant explained to the Examiner that Reiley could not anticipate the claims (as Examiner Reimers clearly understood) because the devices disclosed in Reiley are not capable of being placed on superior and inferior articular facets. Rather than addressing the Applicant's argument as the Examiner is required to do, the Examiner stated in the most recent Advisory Action that somehow the claims are anticipated by Reiley merely because “Reiley calls elements 34 and 76 facet joint elements” and “[e]ach of the elements comprises articulating facet joint implant structure.” (Advisory Action, p. 2). This is not a proper analysis of the claims. The present invention does not include such a broad claim. The claims cannot be anticipated or rendered obvious

¹ Applicant has provided a detailed analysis of why the claims of the present invention are patentable over Louis in hopes of avoiding future piecemeal examination.

by a device merely because it discloses “facet joint elements” where “[e]ach of the elements comprises articulating facet joint implant structure.”

Unfortunately, the Examiner did not stop there. Rather than acknowledge the impossibility of placing the Reiley device **on an articular facet**, the Examiner adopted a new overly broad and wholly unreasonable interpretation to the claims to support his rejection—specifically, that the “claims do not require that the facet be a natural facet.” (See, Advisory Action, p. 2).

The Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly instructed that the claims be given their broadest **reasonable interpretation consistent with the specification**:

The Patent and Trademark Office (“PTO”) determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction ***“in light of the specification as it would be interpreted by one of ordinary skill in the art.”*** *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). Indeed, the rules of the PTO require that application claims must “conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.” 37 CFR 1.75(d)(1).

415 F.3d at 1316, 75 USPQ2d at 1329, emphasis added.

Anyone skilled in the art would understand that the superior and inferior facets of the claims are elements of a vertebra of the spine. There is simply no other reasonable interpretation of the claims. Moreover, the specification of the application specifically defines these terms with reference to the human spine. (Page 5, lines 18-22; Fig. 3). The Examiner’s position that the previously examined claims “do not require that the facet be a natural facet” ignores the Federal Circuit’s clear instruction in *Phillips* and a multitude of prior similar cases. Thus, although the claims have been amended to specify the superior and inferior articular facets as being part of a natural facet, it is submitted that such amendments does not introduce any new question of patentability.

Applicant anticipates that the Examiner will withdraw the rejection and issue a notice of allowance with respect to the pending claims.

Conclusion

It is submitted that this application is in condition for allowance and an early action to that effect is earnestly solicited. In the event that the Examiner has any questions regarding the arguments presented herein, the Examiner is invited to contact the Applicant's representative.

Respectfully submitted,

RENNER, OTTO, BOISSELLE & SKLAR, LLP

By /Mark C. Johnson/
Mark C. Johnson, Reg. No. 51,854

1621 Euclid Avenue
Nineteenth Floor
Cleveland, Ohio 44115
(216) 621-1113